













The MPEP also states that an example of a type of claimed statutory process is "[a] digital filtering process for removing noise from a digital signal comprising the steps of calculating a mathematical algorithm to produce a correction signal and subtracting the correction signal from the digital signal to remove the noise" (MPEP § 2106, paragraph IV.B.2(b)(ii), page 2100-18). Clearly, this exemplary statutory process sets forth a mathematical algorithm including calculations, but does not set forth any machine, e.g., computer hardware or software components.

A machine or method claim is statutory when the machine or method, as claimed, "produces a concrete, tangible and useful result" (MPEP § 2106, paragraph IV.B.2(b)(ii), page 2100-18, citing *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1358 (Fed. Cir. 1999) and *State Street Bank & Trust Co. v. Signature Financial*, 149 F.3d 1368, 1373 (Fed. Cir. 1998)). The invention set forth in the pending claims includes a transformation of data to produce a useful, concrete, and tangible result. For example, a transformation of data occurs when the viscoelastic properties of the second order components are used to determine a viscoelastic property of the first order region of macroscopic bone. This transformation of data produces a useful, concrete, and tangible result which is the properties of the first and second order components. These properties are used to study or predict the behavior of the bone, e.g., when it is subject to an external force. The predictions of the behavior of bone can be used, for example, to improve the fitting of implants. The behavior of the bone subject to the external force can also be used to study deformation and fracture in the bone.

For the aforementioned reasons, the subject matter of the claims is statutory with or without the recitation of computer hardware or software components.

Based on the foregoing, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn, and reconsideration is respectfully requested.























can be measured; it does not teach or suggest incorporating angle-of-twist as a function of torque, strain rate, or time into a model of bone, nor measuring it for that purpose.

*E. Crolet, Carter, Wolfinbarger, and Ascenzi '93 (Claims 22 and 23)*

Claims 22 and 23 have been rejected as being unpatentable over Crolet in view of Carter and further in view of Wolfinbarger and Ascenzi '93. Applicant respectfully traverses this rejection, and reconsideration is respectfully requested.

Claim 23 has been amended to depend from claims 17, 30, and 31 and discloses incorporating angle-of-twist as a function of torque. Claim 22, as described above, recites that the viscoelastic property is angle-of-twist as a function of torque, osteon hydroxyapatite content, strain rate, or time. The claim has been amended to disclose the experimental steps that are taken to determine the angle-of-twist as a function of torque based on a torque vs. angle-of-twist curves that are determined from torsional testing of various samples of bone.

The Office Action contends that Crolet, Carter, and Wolfinbarger teach the bone model recited in the claims and that Ascenzi '93 discloses angle-of-twist as a function of torque. However, as noted above, these references do not disclose or suggest a model in which the second order components, e.g., osteons, trabeculae, and lamellae, are non-homogeneous or a model that incorporates a hierarchical structure in which the viscoelastic properties of second order components are used to help predict the behavior of a first order macroscopic region of bone. Furthermore, Ascenzi '93 does not teach or suggest incorporating angle-of-twist as a function of torque into a model of bone, nor measuring it for that purpose using data derived from experiments using samples of bone.

*F. Crolet, Ascenzi '99, Lakes, and Ascenzi '93 (Claim 16)*

Claim 16 has been rejected as being unpatentable over Crolet in view of Ascenzi '99 and Lakes and further in view of Ascenzi '93. Applicant respectfully traverses this rejection, and reconsideration is respectfully requested.





Ascenzi '93 discloses that fractures occur when torque is applied to experimental bone samples (Ascenzi '93, page 881, column 1, paragraph 4, to column 2, paragraph 2). However, Ascenzi '93 does not disclose a bone model for predicting deformation and fracture. Ascenzi '93 only hypothesizes on the location of fracture; it does not disclose the steps of calculating stress and strain distributions and making comparisons to determine where fracture occurs in a bone model.

*I. Crolet, Ascenzi '99, Lakes, Copland, and Agrawal (Claim 19)*

Claim 19 has been rejected as being unpatentable over Crolet in view of Ascenzi '99 and Lakes and further in view of U.S. Patent No. 6,333,313 to Copland ("Copland") and U.S. Patent No. 5,947,893 to Agrawal et al. ("Agrawal"). Claim 19 has been canceled without prejudice and the rejection is moot.

*J. Crolet, Carter, Wolfinbarger, Hamamoto, and Ascenzi '97 (Claim 26)*

Claim 26 has been rejected as being unpatentable over Crolet in view of Carter and Wolfinbarger and further in view of U.S. Patent No. 5,732,469 to Hamamoto et al. ("Hamamoto") and Ascenzi, "X-ray diffraction on cyclically loaded osteons," August 1997, ("Ascenzi '97"). Applicant respectfully traverses this rejection, and reconsideration is respectfully requested.

Claim 26 depends from claim 31, 30, and 17 and has been amended to state that the viscoelastic property of the second order components is modified based on collagen-bundle directions of the selected bone, the method further comprising the step of determining collagen-bundle directions of the samples using circularly polarizing light microscopy, confocal microscopy or X-ray diffraction of the samples.

The Office Action contends that Crolet, Carter, and Wolfinbarger teach the bone model recited in the claims. However, as noted above, Crolet, Carter, and Wolfinbarger do not disclose or suggest a model in which the second order components, e.g., osteons, trabeculae, and



If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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